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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/058,522 | 01/28/2002 | Mark James Batchelor | VPI/96-01 CIP2 DIV3 | 4312 |
| 1473 | 7590 | 05/27/2004 | EXAMINER | |
| FISH & NEAVE 1251 AVENUE OF THE AMERICAS 50TH FLOOR NEW YORK, NY 10020-1105 | | | KIFLE, BRUCK | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1624 | |

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/058,522

Applicant(s)

BATCHELOR ET AL.

Examiner

Bruck Kifle, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/18/03; 03/4/04 and 03/11/04.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 68 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 38-40,42,55-57,62,66,68,79-83,88-93,95,96,98-100,102,104,112,114,118-131,133-135,138,139 and 154-270.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 38-40,42,55-57,62,66,79-83,88-93,95,96,98-100,102,104,112,114,118-131,133-135,138,139 and 154-270.

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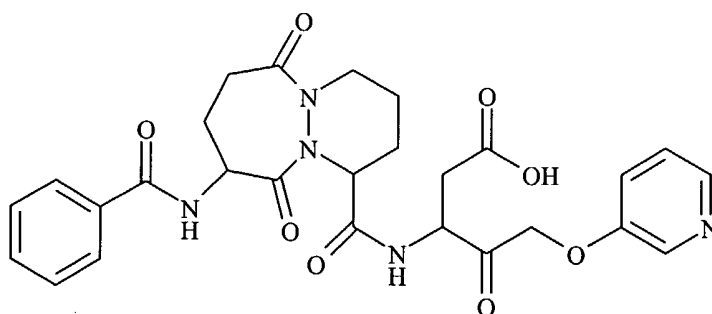
Applicant's amendments and remarks filed 12/18/03 have been received and reviewed. Supplemental responses filed 3/04/04 and 3/11/04 have also been received and entered.

Claims 38-40, 42, 55-57, 62, 66, 68, 79-83, 88-93, 95, 96, 98-100, 102, 104, 112, 114, 118-131, 133-135, 138, 139 and 154-270 are now pending in this application.

Election/Restrictions

Applicant's election of compound 283 recited in claim 40 in the paper filed 12/18/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The elected compound has the structure



This compound was not found in the search and, therefore, the search was expanded to embrace the entire scope of claim 68.

Note that compounds, corresponding compositions, a method of use and a process of making that are of the same scope are considered to form a single inventive concept. The instant claims are not so linked as to form a single inventive concept. The compounds are so diverse in scope that a prior art anticipating one compound under 35 USC 102 would not render obvious another compound of the same claim under 35 USC 103.

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Claims 38-40, 42, 55-57, 62, 66, 79-83, 88-93, 95, 96, 98-100, 102, 104, 112, 114, 118-131, 133-135, 138, 139 and 154-270 because art is found. (See MPEP 803.02.)

Applicants are also advised of MPEP 803.02 Restriction - Markush Claims [R - 2], fourth paragraph, where is stated;

“As an example, in the case of an application with a Markush - type claim drawn to the compound C - R, wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD, or CE. The Markush - type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush - type claim and claims to the elected species shall be rejected, and claims to the non - elected species would be held withdrawn from further consideration. As in the prevailing practice, **a second action on the rejected claims would be made final.**” (Emphasis added).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bemis et al. (WO 95/35308). The reference teaches a generic group of structurally similar compounds which are ICE inhibitors which embraces applicants' claimed compounds (See page 36, line 15, formula α and in particular page 51 where R₁ is defined as e2. See also compounds in pages 82 and 83).

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The claims differ from the reference by reciting specific species and a more limited genus than the reference. The species of the reference are excluded by proviso. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. v. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

Compounds of the reference excluded by proviso render the claim obvious. For example, the compound of the reference wherein *m* is 1; R₁₅ is -OH; R₂₁ is -H; Y is O; R₃ is -C(O)-H and R₅ is -C(O)-R₁₀, wherein R₁₀ is Ar₃ and the Ar₃ cyclic group is phenyl is excluded by proviso. However, the compound wherein ***m* is 2**; R₁₅ is -OH; R₂₁ is -H; Y is O; R₃ is -C(O)-H and R₅ is -C(O)-R₁₀, wherein R₁₀ is Ar₃ and the Ar₃ cyclic group is phenyl is embraced by the claim. It has been long established that structural relationship varying the size of a linking carbon chain - is per se obvious. Specifically, *In re Shetty*, 195 USPQ 753, *In re Wilder*, 195 USPQ 426 and *Ex Parte Gresham* 121 USPQ 422 all feature a compound with a C₂ link rejected over a compound with a C₁ link. Similarly, *In re Chupp*, 2 USPQ 2nd 1437 and *In re Coes*, 81 USPQ 369 have a C₁ link unpatentable over a C₂ link. *Ex parte Ruddy* 121 USPQ 427 has a C₃ link unpatentable

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over a C₁ link. Ex parte Nathan, 121 USPQ 349 found the insertion of a C₂H₄ link obvious. In all of these cases, the variation was per-se obvious and did not require a specific teaching.

Similarly, homologues and ring position isomers of the compounds of the prior art, which are excluded herein by proviso, render the claim prima facie obvious. For example, a compound of the instant claim, which has a 3-fluorophenyl group, is rendered obvious by the compound of the reference that differs only by having a 2-fluorophenyl group.

Applicants are advised of the reference WO 95/33751 which would raise obviousness issues. While this is not a rejection, Applicants are advised thereof as a courtesy.

Copious amount of provisos are present in claim 68. If these provisos are present to avoid prior art, Applicants are urgently requested to point to these compounds in the prior art because the disclosure of these compounds is material to the examination of the instant claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle, Ph.D. whose telephone number is 571-272-0668. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund J. Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Bruck Kifle, Ph.D.
Primary Examiner
Art Unit 1624

BK
May 26, 2004